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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/790,540	01/30/97	HUSE	P-IX-2405

EXAMINER

HM22/0318

GAMPBELL UNIT	PAPER NUMBER
1644	16

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DATE MAILED: 03/18/99

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 2/9/99; 12/14/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-25 is/are pending in the application.
Of the above, claim(s) 19-25 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-18 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10, 15
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group Art Unit 1644.

2. The request filed 2/9/99 (Paper No. 14) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/790,540 is acceptable and a CPA has been established An action on the CPA follows.

3. Applicant's After Final Amendment, filed 12/14/98 (Paper No. 12), has been entered.. Claims 1-18 have been amended.

Applicant has introduced the Sequence Listing, filed 6/9/98 (Paper No. 9) into the specification by formal amendment.

4. A restriction was required under 35 USC § 121 in the parent application, Paper No. 5 between one of the following Groups:

I. Claims 1-18, drawn to vitaxin/LM609 CDR-grafted-specific antibodies and nucleic acids encoding said antibodies.

II. Claims 19-25, drawn to method of treatment with vitaxin/LM609 CDR-grafted-specific antibodies..

Applicant elected Group I, claims 1-18 with traverse. This restriction requirement is hereby reiterated. Accordingly, claims 19-25 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-18 are under consideration in the instant application.

5. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 12/14/98 (Paper No. 12). The rejections of record can be found in previous Office Actions (Paper Nos. 5/8/13).

It is noted that New Grounds of Rejection based upon 102(e) and 102(f) have been set forth herein.

It is noted that New Grounds of Rejection based upon 102(e) and 102(f) have been set forth herein. Applicant's arguments concerning the prior art rejections of record have been fully considered but have not been found convincing essentially for the reasons of record. However, these arguments are rendered moot in view of applying U.S. Patent No. 5,753,230.

6. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 3/6/98 (Paper No. 7). The rejections of record can be found in previous Office Actions (Paper Nos. 5/8/13).

7. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 5.
Applicant is reminded to amend the specification to correspond to how the figures will be corrected

8. Claims 1- 18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of copending application USSN 08/791,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to the same or nearly the same vitaxin-specific antibodies and nucleic acid encoding said antibodies and modifications thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are directed to an invention not patentably distinct from claims 1-48 of commonly assigned USSN 08/791,391.

Commonly assigned USSN 08/790,540, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78© to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

Applicant's amendment, filed 12/14/98 (Paper No. 12), reiterates applicant's previous amendment, filed 3/6/98 (Paper No. 7), to indicate that the provisional grounds of rejection be deferred until there is an indication of allowable subject mater..

9. Claims 1-18 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Upon reconsideration of applicant's amended claims, filed 12/14/98 (Paper No. 12); the previous rejection under 35 U.S.C. § 112, first and second paragraphs, as it applies to "functional fragment thereof" has been withdrawn

Applicant's arguments, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 5/8/13) as it applies to the recitation of "substantially the same".

Applicant submits that the terms "substantially the same" are clear to the skilled artisan in view of the specification. Applicant relies upon pages 12-14 of the instant specification to indicate that "substantially the same" encompasses a considerable degree, amount of or extent of sequence identity when compared to a reference sequence. Here, a nucleotide or amino acid sequence which is substantially the same as a heavy or light chain of LM609 or LM609 CDR-grafted antibody is a sequence which exhibits characteristics that are recognizable as encoding or being the amino acid sequence of LM609 or a LM609, including minor modifications.

However, as applicant acknowledges, such phrases or terms encompass a considerable degree of modifications. In addition, applicant asserts reliance upon recognizable characteristics without defining the metes and bounds of said recognizable characteristics (e.g. structural and/or functional). While applicant argues $\alpha_v\beta_3$ binding activity or binding specificity in reference to the claimed antibodies, the claimed limitations are drawn to selective binding affinity to $\alpha_v\beta_3$. Applicant argues that "selective binding affinity to $\alpha_v\beta_3$" is descriptive of the claimed antibody comprising substantially the same variable region amino acid sequences as the LM609 CDR-grafted antibody; and , in turn, provide sufficient structural and functional characteristics of the claimed antibodies. Again, the metes and bounds of "substantially the same" is ambiguous and unclear in the context of the claimed limitation versus applicant's asserted limitations of binding specificity and inhibitory activity. Further, it is noted that a percentage of sequence identity is meaningless in the absence of mathematical algorithm employed to calculate such number. Depending on the gap weight, gap length, lengths of two sequences to be compared, etc., a percentage of sequence identity can vary dramatically. If the skilled artisan is not provided with guidance as to the determination of "substantially the same" particularly as it relates to "sequence identity; the skilled artisan one could not determine what is encompassed by "the claimed invention".

As pointed out previously, applicant has argued that the claimed invention encompasses only those LM609 CDR-grafted antibodies having substantially the same heavy and light chain CDR amino acid sequences as found in LM609 and exhibiting $\alpha_v\beta_3$ binding specificity but is not dependent on a particular percentage of sequence identity as defined by a mathematical algorithm. Applicant asserted that once the sequence becomes sufficiently divergent that binding specificity to $\alpha_v\beta_3$ is no longer exhibited, the sequences can no longer be considered substantially the same. The terms and phrases are not defined by the claims, the specification does not provide a sufficient standard for ascertaining the requisite degree or metes and bounds of the claimed "phrase" above and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant's arguments are not found persuasive, particularly as it applies to the recitation of "substantially the same".

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter.

10. Upon reconsideration of applicant's amended claims, filed 12/14/98 (Paper No. 12); the previous rejections under 35 U.S.C. § 112, second paragraph, as they apply to the instant claims have been withdrawn.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows:

As pointed out previously, Biotechnology Newswatch (1/16/95 and 2/6/95) disclose the use of LM609 antibody including the humanized version of said antibody. Also it is noted that Cheresh, who developed the LM609 antibody and who conducted the in vivo experiments, is not listed as an inventor.

Applicant's arguments, in conjunction with the Huse declaration and Exhibit A under 37 C.F.R. § 1.132, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing. It is acknowledged that Huse Declaration and Exhibit A as well as applicant's arguments address the role of Ixsys and Celltech Biologics and confidentiality agreements between these two parties.

While certain nucleic acids and cell lines associated with Vitaxin or the CDR-grafted LM609 antibody were the subject of these agreements; this agreement does not appear to obviate the clear evidence that the humanized LM609 antibody or Vitaxin was made and used by others without apparent obligation or secrecy or restriction and that contracts and commercial exploitation of said Vitaxin were made more than one year prior to applicant's priority date. The claims are not drawn to nucleic acids and cell lines, but rather are drawn to CDR-grafted LM609 antibodies.

Furthermore, the role of Scripps as the licensee and restrictions or confidentiality with respect to Scripps as well as the principal investigator Cheresh as it applies to public use and sale is not clearly addressed.

The objective evidence of record was sufficiently informing to the public of humanizing the LM609, encompassed by the claimed invention. Given the absence of factual circumstances surrounding the activity and how these comport with the policies underlying the "on sale" and "public use" bars, the rejection is maintained. See MPEP 2133.03.

Applicant's arguments are not found persuasive.

14. Claims 1-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Brooks et al. (U.S. Patent No. 5,753,230; 1449). Brooks et al. teach the LM609 antibody as well as humanized forms of this antibody and claim methods of using the LM609 antibody as well as humanized forms of this antibody (see entire document, particularly columns 15-19 and the claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced LM609 antibodies and humanized antibodies thereof.

15. Claims 1-18 are rejected under 35 U.S.C. § 102(f) because the applicants did not invent the claimed subject matter.

Applicant's arguments, in conjunction with the Huse declaration, filed 12/14/98 (Paper No. 12), as well as U.S. Patent No. 5,753,230; 1449) and Biotechnology Newswatch Biotechnology Newswatch (1/16/95) present an ambiguity with regard to the inventorship of the claimed invention.

Applicant's comments including those of Huse indicate that at most Cheresh could be considered a collaborator but not as inventor of the claimed invention. However, applicant has not provided the facts concerning the nature and role of Cheresh as a collaborator, with respect to humanizing the LM609 antibody. It is noted that Biotechnology Newswatch acknowledges that Cheresh was the principal investigator. It is clear that Cheresh developed the LM609 antibody and that it was possible to determine without undue experimentation antibodies and humanized antibodies having the same properties (see U.S. Patent No. 5,753,230, particularly columns 15-19). Further, U.S. Patent No. 5,753,230 claims the use of LM609 antibody as well as humanized versions thereof. Similarly the instant specification acknowledges that Cheresh developed the LM609 antibody (see page 9, for example) and that generating humanized/CDR-grafted antibodies were known in the art at the time the invention was made (see page 17, for example).

Also, it is noted that the Huse Declaration indicates that he conceived the idea of humanizing $\alpha_v\beta_3$ inhibitory antibodies, while it is clear given U.S. Patent No. 5,753,230 that was known in the prior art by others.

Also, given Huse Declaration of sole conception, it is not clear what role coinventor Glaser provided in the claimed invention.

Also, given that Brooks is an inventor on U.S. Patent No. 5,753,230; it is not clear why he as well as Cheresh are not inventors of the instant invention.

To resolve the ambiguity, applicants may file declarations by the non-applicant s Cheresh and Brooks disclaiming the invention or a declaration by applicant setting forth the facts which provide an explanation as to why the non-applicant are not inventors. Further, applicant may provide facts why Glaser is an inventor.

16. Claims 1, 15-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brooks et al. (Cell, 1994; 1449) for the reasons of record set forth in Paper Nos. 5/8/13.

Applicant's arguments, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing for the reasons of record set forth in Paper Nos. 4/8/12. Applicant's argues that the claimed antibodies have human acceptor framework sequences with LM609 CDRs and therefore are not mouse antibodies, and in turn, do not teach the structural characteristics of the claimed antibodies. Also, applicant argues that "substantially the same" refers to a sequence which exhibits characteristics that are definitely known or recognizable as representing the amino acid sequence of Vitaxin or a LM609 antibody and not LM609. However as pointed out previously, applicant's specification and arguments, including those filed in Paper No. 5, have indicated that "substantially the same" encompasses LM609 or LM609 grafted antibody. Also, for the reasons of record, the interpretation of "substantially the same" does encompass antibodies having the characteristics of Vitaxin or the LM609 antibody and the LM609 does have functional as well as structural characteristics encompassed by "substantially the same". Given the breadth of the claims to read on the LM609 antibody, applicant's arguments are not found persuasive. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

Applicant's arguments are not found persuasive

17. Claims 1, 15-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Choi et al. (J. Vasc. Surg., 1994; 1449) for the reasons of record set forth in Paper Nos. 5/8/13.

Applicant's arguments, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing for the reasons of record set forth in Paper Nos. 5/8/13. Applicant's arguments and the examiner's rebuttal are essentially the same as set forth above in Section 14 with respect to the interpretation of "substantially the same".

Applicant's arguments are not found persuasive

18. Claims 1, 15-18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kim et al. (U.S. Patent No. 5,578,704) for the reasons of record set forth in Paper Nos. 5/8/13.

Applicant's arguments, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing for the reasons of record set forth in Paper Nos. 5/8/13. Applicant's arguments and the examiner's rebuttal are essentially the same as set forth above in Section 14 with respect to the interpretation of "substantially the same".

Applicant's arguments are not found persuasive

19. Claims 1-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Brooks et al. (U.S. Patent No. 5,753,230; 1449) OR Brooks et al. (Cell, 1994; 1449) OR Choi et al. (J. Vasc. Surg., 1994; 1449) OR Kim et al. (U.S. Patent No. 5,578,704) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 3-37 or Examples I and II of the instant specification or as cited by references on the 1449 for the reasons of record set forth in Paper Nos. 5/8/13.

The teachings of Books et al. (Cell, 1994; 1449) OR Choi et al. (J. Vasc. Surg., 1994; 1449) OR Kim et al. (U.S. Patent No. 5,578,704) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 10-39 or Examples I and II of the instant specification or as cited by references on the 1449 are of record

Newly added Brooks et al. . (U.S. Patent No. 5,753,230) teach the LM609 antibody as well as humanized forms of this antibody and claim methods of using the LM609 antibody as well as humanized forms of this antibody (see entire document, particularly columns 15-19 and the claims). With respect to specific amino acid changes including those which are "substantially the same" would be obvious given the teachings of humanized LM609 antibodies and art known methods to generate such humanized antibodies which retain the desired functional characteristics of the native antibody and to alter said antibody for therapeutic uses, including human therapy, as taught and known in the prior art.

Applicant's arguments, filed 12/14/98 (Paper No. 12), have been fully considered but are not found convincing for the reasons of record set forth in Paper Nos. 5/8/13. Applicant arguments essentially focus on whether the prior art taught the structural features of the LM609 antibody, particularly the nucleic acid or amino acid sequences of the LM609 antibody. Applicant's arguments concerning Bell, Deuel and Goldgaber are acknowledged and the examiner's rebuttal are of record.

Here, it is noted that the newly added Brooks et al. (U.S. Patent No. 5,753,230) clearly provides the teachings of the obviousness of humanized LM609 antibodies, encompassed by the claimed invention.

As pointed out previously; the amino acid and nucleic acid sequences associated with the LM609 antibody including those of humanized LM609 antibodies would have been available to the ordinary artisan, given the availability of the LM609 antibody and hybridoma together with general immunoglobulin gene cloning and expression strategies. It would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate chimeric or humanized LM609 antibodies, DNA encoding said antibodies. Given the highly conserved nature of immunoglobulin gene organization and structure and the availability of probes and PCR primers for immunoglobulin gene cloning, one of ordinary skill in the art could have isolated the functionally rearranged heavy and light chain variable regions from the LM609 hybridoma cell line and determined their sequences with a complete expectation of success. For example, the ordinary artisan does not need to determine the amino acid sequences of a rearranged V (variable) region before cloning. The claims do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected to obtain given the known LM609 hybridoma thereof, the known heavy and light chain and the art known techniques regarding the production of chimeric antibodies, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement. The claimed DNA sequences must encode a recombinant antibody comprising heavy and/or light chain variable regions of the LM609 antibody.

Immunoglobulin gene structure and organization were well understood in the art a the time the claimed invention was made and that strategies for cloning the DNAs encoding immunoglobulin variable regions genes were well established in the art at the time the claimed invention was made, as were methods for the production of DNA constructs encoding immunoglobulin variable regions. In addition, it was known at the time the invention was made that the benefits of producing recombinant antibodies to reduce the immunogenicity of therapeutic and diagnostic antibodies in human patients. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant has not provided any objective evidence to indicate that the resulting amino acid or nucleotide sequences were unobvious at the time the invention was made. As pointed out in the previous Office Action, it was noted that the instant disclosure relied upon standard humanization procedures to derive the claimed antibody and nucleic acid compositions. Also, it is noted that Biotechnology Newswatch (1/16/95 and 2/6/95) references above support the routine nature of providing an antibody/hybridoma of interest to a commercial interest to develop humanized antibodies and the nucleic acids encoding said antibodies by routineers in the art at the time the invention was made. Applicant argues that the claimed compositions are directed to Vitaxin and LM609 grafted antibodies and nucleic acids encoding said antibodies in contrast to the prior art teachings of LM609 antibody. However, applicant's specification and arguments, filed in Paper No. 6, also indicate that "substantially the same" encompasses LM609, Vitaxin or LM609 grafted antibody. Given the breadth of the claims to read on the LM609 antibody, the instant antibodies and nucleic acids read on a genus of antibodies and nucleic acids encompassed by LM609 and modifications thereof.

Applicant's arguments are not found persuasive.

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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